DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2014

Nordic NeuroLab AS
% Mr. Chandana Gurung Bhandari
Mollendalsveien 65 C
N-5009 Bergen
NORWAY

Re: K140956
Trade/Device Name: LCD Monitor
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: June 27, 2014
Received: July 7, 2014

Dear Mr. Bhandari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
140956

Device Name
LCD Monitor

Indications for Use *(Describe)*
The LCD monitor is intended to be used by trained professionals as a fMRI viewing monitor within the MR environment.

This device must not be used for a life support system.
This device must not be used for diagnostics.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
NordicNeuroLab AS
NNL Monitor

Submitter: NordicNeuroLab AS
Møllendalsveien 65C
N-5009 Bergen
Norway
Phone: +47 55 70 70 95
Fax: +47 55 70 70 96

Primary Contact: Chandana Gurung Bhandari (chandana@nordicneurolab.com)

Proprietary Name:	LCD Monitor
Device Common Name:	Accessory to MRI system, Nuclear Magnetic Resonance Imaging System, image processing, radiological
Classification Regulation:	21 CFR 892.1000
Class:	II
Panel:	Radiology
Product Code:	LNH
Predicate device name:	fMRI Hardware System

Device Description

The LCD Monitor is designed for the purpose of viewing images for MRI applications within the MR environment. The high resolution panels combined with high performance image processing controller, provides the users extremely high definition and high quality medical image displays. The monitor comply with international EMC and safety standards for medical devices.

Intended Use

The LCD monitor is intended to be used by trained professionals as an fMRI viewing monitor within the MR environment.

This device must not be used for a life support system.

This device must not be used for diagnostics.

Technological Characteristics and Substantial Equivalence

In all material respects, the LCD monitor is similar to the predicate device NordicNeuroLab fMRI hardware (K092253-LNH Subsystem - Visual system- in- room LCD Monitor). Testing was performed according to the internal company procedures and the monitor was safety certified to international standards.

Though some differences between the new devices and the predicate device exist, these differences do not raise new questions of safety and effectiveness.

Compliance and Voluntary standard compliance

The subject device has been tested against and has passed the following standards:

- **IEC 60601-1:2005,** General Requirements for Electrical Safety
- **IEC 60601-1-2:2007,** Electromagnetic Compatibility

Performance Testing

Prospectively defined verification and validation activities for the LCD Monitor assure that it meets all design and performance specifications as well as user needs when operated according to the operating instructions (Section 18).